

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE LITIGATION)	MDL No. 1456
)	
)	Civil Action No. 01-CV-12257 PBS
)	
THIS DOCUMENT RELATES TO)	
<u>COMMONWEALTH OF MASSACHUSETTS V.</u>)	Hon. Patti B. Saris
<u>MYLAN LABORATORIES, INC. ET AL., CIV.</u>)	
ACTION NO. 03-11865-PBS)	

**DEFENDANTS' RESPONSE TO THE COMMONWEALTH OF MASSACHUSETTS'
MOTION TO INTERVENE AND MOTION FOR ORDER
ADDING ADDENDUM TO THE 12/13/02 PROTECTIVE ORDER**

Opposing Defendants¹ respectfully submit this memorandum in response to the Commonwealth's motions to intervene in the MDL and to modify the protective order to give it access to confidential materials that were not produced in its case.²

Preliminary Statement

The Commonwealth seeks intervention in this case and modification of the Protective Order entered on December 13, 2002 [Docket No. 276] (the "Protective Order") governing discovery because of a purported "significant discovery disadvantage" in which it

¹ The "Opposing Defendants" joining in this opposition include all manufacturer defendants in the actions that have been consolidated as part of MDL 1456, excluding those manufacturers who are also defendants (and have not settled) in the Commonwealth of Massachusetts' non-consolidated action also pending before this Court. The "Commonwealth Action Defendants" who are not joining in this Opposition are identified at infra note 4.

² See The Commonwealth of Massachusetts' Motion to Intervene for the Limited Purpose of Moving to Add an Addendum to the 12/13/02 Protective Order Permitting the Commonwealth Access to Confidential and Highly Confidential Material (the "Motion to Intervene") and The Commonwealth's Motion for Order Adding Addendum to the 12/13/02 Protective Order Allowing Commonwealth of Massachusetts Access to the Confidential and Highly Confidential Information (the "Motion for Modification," and, together with the Motion to Intervene, the "Motions") [Docket No. 4809].

finds itself in its own non-consolidated, AWP-related action pending before this Court (the “Commonwealth Action”).³ (Mem. in Support of the Mot. for Modification [Docket No. 4809 -3] at 2 (the “Commonwealth Memorandum” or “Commonwealth Mem.”).) The Commonwealth claims that, unlike the remaining defendants in the Commonwealth Action (who are also defendants in one or more of the actions that have been consolidated as part of this MDL) (the “Commonwealth Action Defendants”)⁴ it does not have access to certain discovery materials designated “Confidential” or “Highly Confidential” under the Protective Order and as a result is unable adequately to prepare for certain depositions that are cross-noticed by defendants in both the MDL and in the Commonwealth Action. (Id. at 3-4.) To remedy this alleged imbalance, it seeks a modification of the Protective Order granting it access to all of the Confidential and Highly Confidential discovery produced in the MDL, regardless of whether the Commonwealth has sued the producing party and regardless of the discovery’s relationship to any cross-noticed deposition in the case.

To the extent that the Commonwealth seeks access to confidential information produced by defendants or third parties in this case, who are not parties in the Commonwealth’s case, and that information is not relevant to the depositions for which the Commonwealth claims it needs to prepare, the motion should be denied. There are other less intrusive means available for the Commonwealth to obtain the discovery that it claims it needs, and to which it might otherwise be entitled.

³ Commonwealth of Massachusetts v. Mylan Labs., Inc., Civ. Action No. 03-11865-PBS (D. Mass.).

⁴ A number of defendants in the Commonwealth Action have settled with the Commonwealth. The remaining defendants are: Mylan Laboratories, Inc.; Ivax Corp.; Warrick Pharmaceuticals Corp.; Watson Pharmaceuticals, Inc.; Schein Pharmaceutical, Inc.; Teva Pharmaceuticals USA, Inc.; Par Pharmaceutical, Inc.; Purepac Pharmaceutical Co.; and Roxane Laboratories, Inc.

Background

Pursuant to the Protective Order, “producing part[ies]” in any of the actions consolidated in the AWP Litigation were permitted to designate produced discovery material as “Confidential” or “Highly Confidential,” (together, “Confidential Material”).⁵ The parties also agreed that such material “shall be used or disclosed solely for the purpose of the AWP Litigation” and not “for any business purposes, or in any other litigation or other proceeding, or for any other purpose, except by Court Order or otherwise required by law.” (Protective Order ¶ 8.) All discovery in the AWP Litigation was undertaken and produced after the entry of the Protective Order, and in reliance upon the protections afforded therein.

On September 25, 2003, the Commonwealth filed its initial complaint in the Commonwealth Action. The allegations in the Commonwealth Action were limited to certain generic companies. See Mylan Labs., First Am. Compl. ¶ 1 (May 19, 2005) [Docket No. 97] (attached hereto as Ex. A). The complaint asserts no claims as to dozens of other defendants in one or more of the actions consolidated as part of the AWP Litigation that are not also Commonwealth Action Defendants.

⁵ Material designated “Confidential” under the order is “limited to information that any producing party, including any third party, in good faith, believes to contain (a) proprietary or commercially sensitive information; (b) personal financial information; or (c) information that should otherwise be subject to confidential treatment under Rule 26(c)(7) of the Federal Rules of Civil Procedure.” (Protective Order ¶ 3.)

Material designated “Highly Confidential” under the Order is “limited to information that any producing party, including third parties, in good faith, believes to contain (a) current and past (to the extent they reflect on current) methods, procedures and processes relating to the pricing of pharmaceuticals; (b) current and past (to the extent they reflect on current) marketing plans and methods; (c) current and past (to the extent they reflect on current) business planning and financial information; (d) trade secrets; (e) past or current company personnel or employee information; and (f) other ‘Confidential Information’ (as defined in Paragraph 3) the disclosure of which is likely to cause competitive or commercial injury to the producing party.” (Id. ¶ 5.)

On November 21, 2006, the Commonwealth moved to modify the protective order entered in the Commonwealth Action to permit the Commonwealth “to disclose to any agency or department of the United States, or any division of any such agency or department, or to any agency or department of any state or political subdivision thereof, CONFIDENTIAL information relating to any potential violation of law or regulation, or relating to any matter within that agency’s jurisdiction.”⁶ That motion was denied on October 29, 2007. See Mylan Labs., Slip Op. at 16 (Oct. 29, 2007) [Docket No. 379] (attached hereto as Ex. C). In denying the motion, Magistrate Judge Collings held that “the amorphous and wide-ranging disclosure contemplated in the proposed modification” would “eviscerate the effectiveness of the protective order” and “would do nothing to advance the present litigation.” Id. at 10.

During the course of discovery in the Commonwealth Action, the Commonwealth Action Defendants have cross-noticed into the Commonwealth Action the depositions of certain third party witnesses taking place in the AWP Litigation. These witnesses are affiliated with the Center for Medicare and Medicaid Services (“CMS”) (16 witnesses), First Databank (1), AmerisourceBergen Corp. (1), Cardinal Health, Inc. (“Cardinal”) (1) and McKesson Corp. (3).⁷ Some of the materials produced in the AWP Litigation by these third parties are Confidential Material under the Protective Order. The Commonwealth has successfully quashed the notices

⁶ Mylan Labs., Pl. Commonwealth of Mass. Mem. in Support of its Mot. to Modify Protective Order to Permit Sharing of Discovery Materials with Other State and Fed. Law Enforcement Personnel at 2 (Nov. 21, 2006) [Docket No. 222] (attached hereto as Ex. B).

⁷ For the Court’s convenience, attached hereto as Exhibit D are true and correct copies of two exemplars of the various cross-notices of depositions at issue. Exhibit D-1 is the Cross-Notice of Deposition of Thomas Scully, the former Administrator of CMS, first served on April 9, 2007. Exhibit D-2 is the Cross-Notice of Deposition of the wholesaler Cardinal, first served on August 24, 2007.

for the First Databank and AmerisourceBergen witnesses.⁸ On October 23, 2007, the Commonwealth filed the instant Motions in this Court,⁹ alleging that the terms of the 12/13/02 Protective Order prevent it from accessing Confidential Material that is relevant to these cross-noticed third party depositions. On October 30, 2007, discovery closed in the Commonwealth Action.¹⁰

Legal Standard

The standard for modification of an existing protective order is context-dependent and varies according to the identity of the party seeking modification and the reasons for which modification is being sought.¹¹ In general, a third party seeking to modify a protective order bears the burden of showing good cause for the modification. SmithKline Beecham Corp. v. Synthon Pharm. Ltd., 210 F.R.D. 163, 166 (M.D.N.C. 2002); see also United States ex rel. Franklin v. Parke-Davis, 210 F.R.D. 257, 258 (D. Mass. 2002) (“A protective order is always

⁸ See Mylan Labs., Electronic Orders (Sept. 13, 2007 & Oct. 4, 2007) (Docket Report excerpts attached hereto as Exhibit E).

⁹ The Commonwealth first moved in the Commonwealth Action for modification of the 12/13/02 Protective Order, but that motion was rejected by Magistrate Judge Collings on the ground that “any motion to modify the protective order in [the AWP Litigation] must be filed in that case and not in the instant case.” (Commonwealth Mem. Ex. B.)

¹⁰ See Mylan Labs., Joint Mot. to Extend Certain Deadlines (July 31, 2007) (entered electronically Aug. 1, 2007) [Docket No. 303] (“8/1/07 Scheduling Order”) (attached hereto as Ex. F).

¹¹ For a court to grant permissive intervention under Rule 24(b), the “applicant’s claim or defense and the main action [must] have a question of law or fact in common,” and intervention must not “unduly delay or prejudice the adjudication of the rights of the original parties.” Fed. R. Civ. P. 24(b). In addition, a court may consider “whether the applicant will benefit by the intervention, whether the intervenor’s interests are adequately represented by other parties, and whether the intervenors will significantly contribute to the full development of the underlying factual issues in the suit and to the just and equitable legal questions presented.” Langone v. Flint Ink N. Am. Corp., 231 F.R.D. 114, 121 (D. Mass. 2005). Here, Opposing Defendants do not contest the propriety of the Commonwealth’s Motion to Intervene apart from its Motion for Modification; however, to the extent that the Commonwealth “will [not] benefit by the intervention” because its Motion for Modification is defective, id., the Court should deny the Commonwealth’s Motion to Intervene.

subject to modification or termination for good cause.” (quoting The Manual for Complex Litigation (Third) § 21.432 (1995)). However, courts require a more exacting standard of demonstrating “extraordinary circumstances” or “compelling need” from governmental third party applicants with investigatory and law enforcement powers, see, e.g., Public Citizen v. Liggett Group, Inc., 858 F.2d 775, 791 (1st Cir. 1988) (limiting the “extraordinary circumstances” test to the context of “government intervention”), whereas courts look more favorably on third party applicants who are litigants in other actions merely seeking to avoid undertaking duplicative discovery to which they would otherwise be entitled, see, e.g., Grove Fresh Distrib., Inc. v. Everfresh Juice Co., 24 F.3d 893, 896 (7th Cir. 1994) (“Where an appropriate modification of a protective order can place private litigants in a position they would otherwise reach only after repetition of another’s discovery, such modification can be denied only where it would tangibly prejudice substantial rights of the party opposing modification.”).

Even where a third party’s motion for modification is premised on the avoidance of duplicative discovery, however, “the collateral litigant must demonstrate the relevance of the protected discovery to the collateral proceedings and its discoverability therein.” Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1132 (9th Cir. 2003). This requirement “prevents collateral litigants from gaining access to discovery materials merely to subvert limitations on discovery in another proceeding.” Id. Moreover, “the movant still should show the inability to reasonably obtain the information by alternative means.” SmithKline Beecham Corp. v. Synthon Pharm. Ltd., 210 F.R.D. 163, 166 (M.D.N.C. 2002). That is because courts should hesitate “to modify protective orders for matters unrelated to the litigation in front of [them] because otherwise, in the long run, parties may begin to distrust protective orders.” Id. Finally, even if duplicative discovery could be avoided by permitting modification of a protective order,

modification may nevertheless be denied if it would “tangibly prejudice substantial rights of the party opposing modification,” United Nuclear Corp. v. Cranford Ins. Co., 905 F.2d 1424, 1428 (10th Cir. 1990), including the right to rely on the confidentiality provisions of a protective order, Griffith v. Univ. Hosp., L.L.C., 249 F.3d 658, 662-63 (7th Cir. 2001).

Argument

I. THE COMMONWEALTH’S BROAD REQUEST ENCOMPASSES CONFIDENTIAL MATERIAL THAT IS IRRELEVANT TO ITS CLAIMS AND NO LONGER PERTINENT TO DISCOVERY IN THE COMMONWEALTH ACTION.

The Commonwealth’s Motions should be rejected to the extent that the relief it requests is vastly more broad than its stated reasons for bringing them.

First, the Commonwealth’s effective request that it obtain access to all Confidential Materials produced in the AWP Litigation – produced by any party or third party to that action, regardless of their relationship to the allegations in the Commonwealth Action – eclipses the bounds of reason. When faced with a collateral litigant seeking access to materials subject to a protective order, a court must satisfy itself that the materials sought are relevant to and would generally be discoverable in the collateral litigation. See Foltz, 331 F.3d at 1132. In Fulbright & Jaworski L.L.P. v. Mariner Health Care, Inc., Civ. No. S-05-CA-1127-FB, 2006 WL 3447688 (W.D. Tex. Nov. 2, 2006), the court rejected the non-party applicants’ efforts to modify a protective order and obtain access to confidential discovery, because the applicants “provide[d] no argument to show the requested information ha[d] any reasonable relationship to” their claim, and that it was “unclear whether the state court [in which the collateral litigation was taking place] would allow the nonparties to discover the documents at issue . . . even if they were not subject to the protective order.” Id. at *5. Here, the Commonwealth complains of needing access to Confidential Material related to the cross-noticed depositions of third party witnesses

affiliated with CMS, First Databank, AmerisourceBergen, Cardinal, and McKesson. However, it has made no showing whatsoever that the Confidential Material produced by the dozens of other AWP Litigation parties and third parties who neither are defendants in, nor have had depositions cross-noticed in, the Commonwealth Action, would be even remotely relevant to its suit against the Commonwealth Action Defendants. To the extent the Commonwealth seeks access to these materials, the Motions should be denied.

Second, it is not even clear what the basis for the Commonwealth's motion is now that discovery in the Commonwealth Action has closed. According to the Commonwealth, plaintiffs in the AWP Litigation are prevented under the Protective Order from sharing with the Commonwealth "AWP Litigation deposition scheduling information, the witness specific documents produced during the course of AWP Litigation, and access to the transcripts and exhibits resulting from numerous AWP Litigation witness depositions." (Commonwealth Mem. at 3.) But the Commonwealth neglects to mention that the entire basis for its Motions has been rendered moot by the close of discovery in the Commonwealth Action on October 30: under the terms of the 8/1/07 Scheduling Order, no further cross-notices of depositions are likely to be permitted.¹² Indeed, were the Court to grant the relief requested by the Commonwealth, it would eviscerate the limitations on discovery in the Commonwealth Action by providing the Commonwealth with access to large volumes of Confidential Material that it would have had no business obtaining in the context of its own suit against the Commonwealth Action Defendants. See 8 Charles A. Wright et al., Fed. Practice & Proc. Civil 2d § 2044.1 (2d ed. 1994) ("If the limitation on discovery in the collateral litigation would be substantially subverted by allowing

¹² Of course, to the extent that the Commonwealth seeks access to the Confidential Materials related to cross-noticed depositions that have already taken place, there are less intrusive alternatives than seeking modification of the Protective Order for obtaining access to those materials. See infra § II.

access to discovery material under a protective order, the court should be inclined to deny modification.”); cf. AT & T Corp. v. Sprint Corp., 407 F.3d 560, 562 (2d Cir. 2005) (affirming denial of collateral litigant’s motion for intervention partly on the ground that the motion “appear[ed] to be an attempt to circumvent the close of discovery in [the] State Court Action”). Accordingly, this Court should deny the Commonwealth’s broad request for modification of the Protective Order.

II. THERE ARE LESS INTRUSIVE METHODS FOR THE COMMONWEALTH TO OBTAIN ACCESS TO THE RELEVANT CONFIDENTIAL MATERIAL IT SEEKS.

“Even when a legitimate reason for the modification [of a protective order] is proposed, such as a need to use the information in other litigation, the movant still should show the inability to reasonably obtain the information by alternative means.” SmithKline Beecham, 210 F.R.D. at 166. This principle gives effect to the reliance placed by parties on the confidentiality provisions of protective orders in undertaking their discovery obligations: “If protective orders were easily modified, … parties would be less forthcoming in giving testimony and less willing to settle their disputes,” and “parties would resort less often to the judicial system for fear that such orders would be readily set aside in the future.” S.E.C. v. TheStreet.com, 273 F.3d 222, 229-30 (2d Cir. 2001).

This principle is especially pertinent where, as here, the party seeking modification of the protective order is a government entity with investigatory and law enforcement power. The parties exchanged Confidential Materials in the AWP Litigation with the express understanding that such information “shall be used or disclosed solely for the purpose of the AWP Litigation” and not “for any business purpose, or in any other litigation or other proceeding, or for any other purpose, except by Court Order or otherwise.” (Protective Order ¶ 8.) Wholesale disclosure of Confidential Materials to a governmental entity with

investigatory and law enforcement powers such as the Commonwealth – especially one that has already attempted to share confidential materials with other state and federal law enforcement personnel – was clearly not contemplated by the parties to the AWP Litigation. See GAF Corp. v. Eastman Kodak Co., 415 F. Supp. 129, 131 (S.D.N.Y. 1976) (While “[t]here is no need to conjecture whether [the parties] construed or considered this understanding with particular reference to the Government as a prospective recipient” of Confidential Material, “it might be supposed that the Government would not have been high on either side’s list of exceptions for its own files.”); see also Palmieri v. New York, 779 F.2d 861, 866 (2d Cir. 1985) (noting that “the state has a special burden with respect to the materials that it seeks to unseal,” and that its investigatory powers “raise a rebuttable presumption against modification”).¹³ This factor further supports the Opposing Defendants’ position that the motion to modify the Protective Order should “be the last resort of [the Commonwealth], not the first.” SmithKline Beecham, 210 F.R.D. at 169.

If for some reason the Commonwealth still requires access to the Confidential Materials related to the depositions that were cross-noticed into the Commonwealth Action and that have already taken place, it can obtain those materials by issuing direct requests to parties in the Commonwealth Action under Fed. R. Civ. P. 34 for the production of documents, or by issuing third-party subpoenas in the Commonwealth Action. See SmithKline Beecham, 210

¹³ Of course, this concern is mitigated by the fact that the Commonwealth in Mylan Laboratories is acting in its proprietary capacity and not in its regulatory or criminal enforcement capacity. See, e.g., Wilk v. Am. Med. Assoc., 635 F.2d 1295, 1300 n.10 (7th Cir. 1981) (suggesting that “if the government institutes a civil suit in its proprietary capacity, without the possible benefit of such special investigatory tools,” it might “be treated as a private litigant” for the purpose of seeking modification of a protective order). However, this is small consolation where, as here, the Commonwealth has previously sought modification of the protective order in the Commonwealth Action to share confidential materials obtained in that case with other federal and state law enforcement officials.

F.R.D. at 168-69 (rejecting an applicant's motion for modification of a protective order, where the applicant's attempt to obtain discovery from a third party "did not involve serving a third-party subpoena"). If the parties from whom documents are sought raise the Protective Order as a bar, then relief can be sought as to those specific documents. This outcome not only preserves the substantial rights and reliance interests of the producing parties in the AWP Litigation, but has the "added benefit of allowing the court in which the main litigation is pending to make the ruling" on the relevance and discoverability of the material at issue. Id. at 169 n.7.

Conclusion

For the reasons expressed above, the Court should deny the Commonwealth's Motions to the extent they seek access to Confidential Materials produced by parties and third parties that have no relationship to the Commonwealth Action.

Dated: November 6, 2007

Respectfully Submitted,

/s/ Jennifer M. Ryan

DWYER & COLLORA, LLP

Thomas E. Dwyer (BBO No. 139660)

Jennifer M. Ryan (BBO No. 661498)

600 Atlantic Avenue

Boston, MA 02210

Tel: (617) 371-1000

Fax: (617) 371-1037

tdwyer@dwyercollora.com

jryan@dwyercollora.com

Steven M. Edwards (SE 2773)

Lyndon M. Tretter (LT 4031)

Thomas J. Sweeney, III (TS 6557)

Admitted *pro hac vice*

HOGAN & HARTSON LLP

875 Third Avenue

New York, NY 10022

Tel: (212) 918- 3000

Attorneys for Defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation and Apothecon, Inc.

CERTIFICATE OF SERVICE BY LEXIS-NEXIS FILE & SERVE

I, James S. Zucker, hereby certify that I am one of Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon, Inc.'s attorneys and that, on November 6, 2007, I caused a copy of **DEFENDANTS' RESPONSE TO THE COMMONWEALTH OF MASSACHUSETTS' MOTION TO INTERVENE AND MOTION FOR ORDER ADDING ADDENDUM TO THE 12/13/02 PROTECTIVE ORDER** to be served on all counsel of record by electronic service pursuant to Paragraph 11 of CMO No. 2 by sending a copy to Lexis-Nexis File & Serve for posting and notification to all parties.

/s/ James S. Zucker
James S. Zucker